Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 17, 2008. Currently, claims 1, 3-10, and 12-32 remain pending. Claims 1, 3-10, and 12-32 have been rejected. With this paper, claims 1 and 23 are amended to correct ordering of the presentation of elements to provide proper antecedent basis for the elements and to better prepare the claims for appeal. No new matter has been introduced by the reordering. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1, 3-10, and 12-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stiger et al. (U.S. Patent No. 6,589,274), hereinafter Stiger, in view of Barry (U.S. Patent No. 5,439,446). After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). In each of the pending independent claims (1, 14, 23, and 27) the relationship between three dimensions of the claimed apparatus is specified. The outer tube has a distal end diameter, the expandable stent has a maximum outer diameter in an unexpanded form, and the inner tube comprises a distal tip having a proximal edge defining an edge diameter. For clarity and reference to the drawings reproduced below,

these dimensions will be referred to as A, B, and C respectively. In the claimed invention, A is greater than or equal to B and C is greater than or equal to B and indicated by the gaps between opposed added arrows. Referring to Figure 3 of the pending application, it will be seen that the necessary elements are present and the relationships found in the pending claims are met:

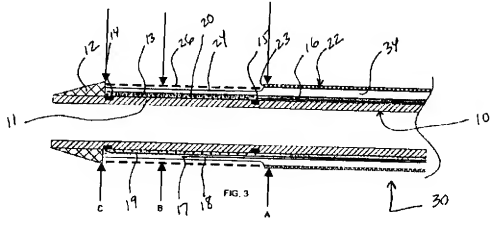
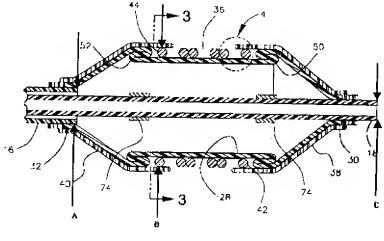


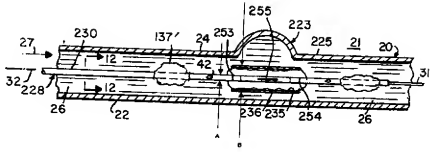
FIG. 3

Turning to the primary reference, Stiger, it will be seen that Stiger lacks a distal tip in the sense of the current claims and so cannot have a proximal edge defining an edge diameter; however the most nearly analogous feature is the distal end of the inner tube of Stiger, here indicated by C. It will be seen that dimension B is significantly greater than either A or C. It should be noted that each of the figures in which the dimensions A, B, and C may directly be compared to the figure above are said to be at least partially inflated. Only Figure 1 of Stiger shows the relative dimensions of outer tube 16, inner tube 18, and balloon 28 in an uninflated state. Figure 1 appears to confirm that the balloon (28) of Fig. 2 of Stiger (below) has an outside diameter significantly greater, by at least a factor of 3, than the outside diameter of the distal end of (16) and is even larger in comparison to the distal end of inner tube 18. Accordingly, even the inner diameter of

stent (36) must be greater than either of the critical dimensions of outer tube (16) and inner tube (18) and so the corresponding relationship taught by Stiger would appear to be A and C are much less than B as would be expected since Stiger does not appear to rely upon the dimensions of the outer and inner tubes to retain the stent over the balloon. Note that in Figure 2, the retaining infolded regions (50,52) of balloon (28) appear to have partially extended distally and proximally without significant radial expansion of the stent (36) as will be seen from the position of the vertical lines representing the proximal and distal ends of the cylindrical portion of the balloon relative to the markers (74) in the later figures.



The secondary reference, Barry, appears to have been presented solely to provide a heating element within the balloon. For completeness, it should be noted that Barry appears to disclose a balloon mounted on a catheter and so fails to provide at least one of an outer tube or an inner tube and so cannot provide the necessary dimensions missing from Stiger. As shown below, the outer dimension of the catheter which most generously might correspond to a distal end diameter, A, is much less than the maximum outer diameter, B, of the stent in an unexpanded form:



Accordingly, Stiger in view of Barry appears to lack the required distal tip having a proximal edge defining an edge diameter. Further, the dimensions of the most nearly analogous features of both Stiger and Barry teach away from the claimed invention by presenting devices in which the maximum outer diameter, B, of the stent in an unexpanded form is much larger than the relevant diameters of the respective shafts and catheter and in which alternate means of retaining the unexpanded stent on the balloon have been selected.

In the Response to Arguments, the Examiner returns to an earlier assertion that Barry discloses a stent delivery system having an expandable stent made of a stent material having a shape memory transition temperature. As discussed previously, nowhere does Stiger or Barry appear to disclose a stent which responds to heating by expanding as found in independent claims 1, 14, 23, and 27. Both Stiger and Barry appear to rely solely upon mechanical expansion of the stent by the underlying balloon. Barry appears to achieve the mechanical expansion of the balloon by heating; however there does not appear to be a disclosure that heating the stent is responsible for expansion of the stent as required by the pending claim. Therefore the Examiner's proposed combination of Stiger and Barry would impermissibly alter the principle of operation of

not just one, but of both references. (MPEP 2143.02, VI.) The Examiner has attempted to overcome the deficiencies of the Barry reference by noting that Barry disclosed a stent made out of nitinol. "Nitinol" appears only once in Barry at col. 6 lines 38-43:

> "The stent 36 may also be formed of a bioabsorbable material, as well as, other known stent constructions (e.g., interlocking loops or mesh formed by filaments, etc.) and materials such as various plastic or metals, including tantalum, stainless steel or nitinol wire."

The Examiner further asserts that

> "Since the stent of Barry is made of the same material, it has the capability of acting in the same manner, expanding when introduced to heat, as that of the application."

In the case of shape memory materials, the view that nitinol is always the same material as nitinol is inappropriate since it is precisely the difference between the crystal structures of the austenite and martensite forms of nitinol which is responsible for the observed response to heating. Barry does not appear to disclose that stents made from nitinol, or any of the other stent materials, require any thermomechanical treatment, other than simple fabrication of the stent, to be suitable for use in an apparatus which relies upon mechanical expansion of an underlying balloon. The stents of the pending application do have the required pretreatment as shown by the presence of a shape memory transition temperature above body temperature. Without such treatment, the nitinol stent disclosed by Barry does not appear to be inherently capable of expanding in response to heat, to the degree required for stent deployment, and Barry does not appear to expect it to do so. The Examiner has failed to show that the nitinol structure of Barry is the nitinol structure of the pending claims. Further, given the apparent lack of

retaining features at proximal and distal ends of the balloons of Barry, it would appear that an expansion in response to warming to body temperature would be undesirable in the stents of Barry in that it would appear to allow the stent to dislodge prematurely from the heated balloon well before the fluid could be heated sufficiently to mechanically expand the balloon as contemplated by Barry, thus tending to render them unsuited for the purpose of Barry.

Therefore, Stiger in view of Barry does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

> "the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (2007)." (MPEP 2141, II.)

The Examiner has failed to identify structures and properties of materials in the cited prior art which correspond to the structures and properties of the most nearly corresponding elements of the pending claims. Specifically, the Examiner has failed to identify a distal tip of an inner tube having a proximal edge defining an edge diameter and an outer tube defining a distal end diameter such that both the edge diameter and the distal end diameter are greater than or equal to the maximum outer diameter of a stent in an unexpanded form, said stent formed of a stent material having a shape memory transition temperature lower than an elevated temperature produced by a heating element positioned around the inner tube proximal to the distal tip. Applicant respectfully asserts that a person of skill in the art would not modify either the stents or the catheters of Stiger

or Barry to include a processing step taught by neither reference in order to provide a property unnecessary, and probably undesirable, in the mechanically expanded devices taught by those references. Therefore, for at least these reasons, Applicants respectfully assert that there is no motivation to combine the teachings of Stiger and Barry and that independent claims 1, 14, 23, and 27are non-obvious in view thereof. Applicants respectfully request that the rejections of independent claims 1, 14, 23, and 27 be withdrawn.

Additionally, for similar reasons, as well as others, claims 3-10, 12-13, 15-22, 24-26, and 28-32, which depend from claims 1, 14, 23, and 27 respectively, and include significant additional limitations, are believed to be patentable over Stiger in view of Barry and Applicant respectfully requests withdrawal of the rejection.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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